Determination of Maximum Therapeutic Benefit (MTB)

Table of Contents

Related Policies

Application of Clinical Algorithms
Experimental and Investigational Services and Devices
The Application of Passive Modalities for Neuromusculoskeletal Disorders
Maintenance/Custodial Care
Critical Data Elements
Skilled Care Services

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Policy Statement

Maximum Therapeutic Benefit (MTB) is determined following a sufficient course of care, where demonstrable improvement would be expected in a patient's health status and one or more of the following are present:

- The patient has returned to pre-clinical/pre-onset health status
- Meaningful improvement has occurred; however, there is no basis for further meaningful improvement
- Meaningful improvement has occurred and there is no basis for further supervised in-office treatment
- The patient no longer demonstrates meaningful clinical improvement, as measured by standardized outcome assessment tools
- Meaningful improvement, as measured by standardized outcome assessment tools, has not been achieved
- There is insufficient information documented in the submitted patient health care record to reliably validate the response to treatment

It is the responsibility of the treating health care provider to maintain a patient health care record that includes periodic measures of treatment response by employing valid, reliable and relevant outcome assessment tools. Further, it is the responsibility of the treating health care provider to include sufficient data in clinical submissions, so that a peer reviewer can render a reasonable determination on baseline status and/or treatment response.

Once MTB has been determined, the treating health care provider is accountable to either:

1. amend the current plan of care based upon current best-evidence
2. refer the patient for an appropriate therapeutic regimen
3. discharge the patient from the current therapeutic regimen

Purpose

This policy has been developed to serve as the clinical criteria for the determination of maximum therapeutic benefit (MTB) in the management of neuromusculoskeletal disorders. Additionally, this policy acknowledges individual health care provider accountabilities in assessing for MTB and appropriate clinical decision-making once MTB has been reached.

Summary

- The application and documentation of standardized patient-reported outcome measures in the management of neuromusculoskeletal disorders is generally viewed as a core component of "best practice"
- The appropriate selection of outcome measurement should be a reflection of the *à priori* development of individual patient treatment goals.
- The assessment of treatment response is critical for determinations about the likely effectiveness of continued treatment and appropriate end-points of care.
- Meaningful clinical change has been calculated for most common standardized (core) outcome assessment tools, which correlate with global perceived effect scales for individual patients
- Recovery patterns for a variety of neuromusculoskeletal conditions generally show rapid improvement (eg, MCID >30%) across outcomes within 4-6 weeks of the index visit for an episode of care regardless of the type of intervention.
- Determinations about the potential for further meaningful clinical improvement can be reliably informed by considering the current response with treatment, factors associated with the patterns of improvement and the longitudinal trajectories of a condition.
- The determination of MTB is based on the potential for further clinically meaningful improvement in the context of the medical necessity for skilled care services by a qualified health care professional.

Scope

This policy applies to all in and out of network programs involving all provider types, where utilization review determinations about maximum therapeutic benefit are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum* by OptumHealth Care Solutions, LLC on the determination of maximum therapeutic benefit.

Definitions

Maximum Therapeutic Benefit (MTB) – The application of the current therapeutic regimen has achieved its full potential benefit for this episode of the condition for which it was applied.

Minimal Clinically Important Difference (MCID) – The smallest change in the OA [outcome assessment] score that the patient perceives as beneficial i.e., clinically meaningful improvement.

Episode of Pain – A period of pain lasting >24hrs, preceded and followed by a period of at least one month without pain.

Episode of Care – Consultation or treatment preceded and followed by at least 3 months without treatment for the same complaint.

Recurrent Pain – Pain that has occurred at least 2 times over the past 12 months with each episode lasting at least 24 hours, and with a pain intensity of >2 on an 11- point numeric rating scale (>20mm on a 100mm visual analog scale), and with at least a 30 day pain-free period between episodes.

Flare-ups/Exacerbations – A flare-up (exacerbation) is a worsening of a patient's condition lasting from hours to weeks that generally impacts usual activities and/or emotions, and is difficult to tolerate with the use of self-care strategies-alone. A flare-up is characterized by significantly increased pain and/or other symptoms and/or pain-related functional limitations, which are equivalent to a clinically meaningful difference on standardized outcome measures. *[Adapted from: Costa N, Ferreira ML, Setchell J, et al. A definition of "flare" in low back pain: a multiphase process involving perspectives of individuals with low back pain and expert consensus. The Journal of Pain 2019;20(11):1267-1275.]*

Consultative Care – Brief episodes of skilled care services that take place on an "as needed" (possibly recurring) basis following the discharge of a patient from a course of planned treatment. Consultative care services may be appropriate for patients who are likely to benefit chronic condition management, where the trajectory is best described in terms of life course vs. episodic.

Background

Overview:

The determination of maximum therapeutic benefit (MTB) is predicated upon several key elements:

1. The timely application and recording of appropriate, valid and reliable measures of treatment response (outcome measures)
2. An adequate period of time and/or treatment trial to reasonably anticipate that meaningful clinical improvement should take place
3. Assessment of clinically meaningful change
4. The probability of further meaningful clinical improvement

Outcome Measurement

Measuring and reporting outcomes is an important component of clinical practice. [1-4] The assessment of treatment response is critical in directing the management of individual patient care, including determinations about the likely effectiveness of continued treatment and appropriate end-points of care.

Standardized outcome assessment tools that are psychometrically sound provide valid and reliable data, which can be used to evaluate the success of an intervention. The use of standardized outcome assessment tools early in an episode of care establishes the baseline status of the patient. Outcomes measured periodically throughout the episode of care provide a means to quantify changes in patient status, including determinations about whether clinically meaningful progress is being realized.

Outcomes assessment includes the application of patient-reported outcome measures (PROMs). These tools qualify the value of health care services from the perspective of attributes identified as important to patients. PROM tools assess how patients feel and what they are able to do by asking questions in the context of a health condition. PROMs provide a means whereby individuals can directly report (self-report) their status without the confounding influence of others eg, clinicians. A patient's subjective responses to the questions/items in PROM tools can be quantified in order to make credible judgments about measurable changes in clinical status.

These tools enable the assessment of patient-important outcomes including pain, function/disability and health-related quality of life.[5] A wide variety of patient-level outcome instruments have been developed for use in clinical settings; many have been evaluated and catalogued within online databases [Table 1]. Commonly used pain scales include the Numeric Rating Scale and the Visual Analogue Scale. Measurement of physical functioning usually takes place using condition-specific questionnaires e.g., Oswestry Disability Index or the Roland-Morris Low Back Pain and Disability Questionnaire.[6]

Table 1. Outcome measurement resources

Source/Sponsor	URL
AbilityLab	https://www.sralab.org/rehabilitation-measures
AbilityLab	https://www.sralab.org/rehabilitation-measures/database
American Physical Therapy Association	http://www.ptnow.org/tests-measures
American Physical Therapy Association	http://www.ptnow.org/FunctionalLimitationReporting/TestsMeasures/
Chiropractic Resource Organization	http://www.chiro.org/LINKS/Outcome_Assessment.shtml
Elon University	http://blogs.elon.edu/ptkids/
Orthopaedic Scores	http://www.orthoscores.com/
Palmer College of Chiropractic	https://www.palmer.edu/research/clinician-research-resource-toolkit/collecting-patient-reported-outcomes-in-the-chiropractic-office/
Physiopedia	https://www.physio-pedia.com/Outcome_Measures
WorkSafe	http://www.worksafe.vic.gov.au/pages/health-professionals/treating-injured-workers/outcome-measures

The appropriate selection of outcome measurement should be a reflection of the *à priori* development of individual patient treatment goals. Choosing the most fit-for-purpose outcome measurement tools is fundamental because using inappropriate instruments can lead to failure to detect meaningful change and/or measurement inconsistency. Typically, outcome tools are selected from among those most frequently used and recommended, having satisfactory measurement properties in the target population.

Evidence-based decision making for the optimal selection, administration, interpretation, and sharing results of outcome measures following a plan of care should take into consideration the:[7]

- Purpose of the measure e.g., applicability with treatment goals and monitoring changes over time
- Population/group for which it is suitable for use e.g., age and diagnosis
- Practicality of the procedure/process e.g., time/work burden
- Psychometric characteristics e.g., reliability, validity, responsiveness, discriminative ability
- Strengths and limitations of the measurement tool or approach e.g., associated costs (licensing fee and equipment/resources), scientific rigor, training requirements, etc.

Global rating scales are typically used to aid in the interpretation of standardized outcome measures. While these scales lack the psychometric rigor of most standardized outcome measures, global ratings make intuitive sense in that they ask individual patients to provide measurable data concerning their subjective judgments about the meaning of change eg, improvement.[8,9] In other words, global rating scales allow patients to express their multidimensional experience from their own viewpoint as to what is important to them in terms of "improvement" or "not-improved."[10] Global ratings that convey responses of "much improved" and "very much improved" are broadly interpreted as clinically meaningful.[8,9,11]

While standardized assessment tools are broadly recommended for use in clinical practice, there may be circumstances when there is no suitable test or important goals are not included in otherwise appropriate tests.[12,13] Goal attainment scaling (GAS) offers an alternative and/or complementary outcome assessment approach.[14] GAS represents a quantifiable method of assessing the extent to which patient's individual goals are achieved (outcomes) in the course of intervention [Table 2]. In effect, GAS results in each patient having their own outcome measure, with it scored in a standardized way as to allow judgments about treatment effectiveness.[14] When goals are appropriately developed, the amount of change between goal scale intervals is regarded as clinically relevant and in equal increments.[15] The goals (usually no more than 3-4 in number) may be weighted to take account of their relative importance, which allows for the calculation of composite GAS scoring as an outcome measure.[14] When using GAS, the following criteria must be satisfied:[15]

- Amount of change between levels is clinically important
- There are approximately equal intervals between levels
- There is a set time period for goal achievement
- Scale reflects a single variable of change (if not feasible, each level reflects a single variable of change)

Table 2. GAS 5-Point Rating Scale

Rating	Goal Attainment Level	Description
– 2	Much less than expected outcome	This level reflects non-clinically relevant changes in performance eg, ranging from regression to no/minor changes during the measurement (intervention) period
– 1	Less than expected outcome	This level reflects performance that is clinically relevant but somewhat less than expected for the intervention period
0	Expected outcome after intervention	Performance to the extent anticipated at the initiation of the treatment plan for the given measurement period
+ 1	Greater than expected outcome	Performance that indicates more progress than expected during the intervention period
+2	Much greater than expected outcome	Performance that reflects significantly more progress than expected during the measurement period

Adapted from: Mailloux Z, May-Benson TA, Summers CA, et al. Goal attainment scaling as a measure of meaningful outcomes for children with sensory integration disorders. *American Journal of Occupational Therapy* 2007;61(2):254–259.

Treatment Response

An understanding of treatment response and recovery patterns assists in the timely identification of progress towards goals, assessment of treatment effect, and identification of end-points in care due to maximum therapeutic benefit.

Progress towards goals can be assessed at points in time following the index visit, when there is a substantiated basis for anticipating meaningful clinical change. These "recovery milestones" represent points in care for follow-up assessment. The recommendations from clinical guidelines and the analyses of systematic reviews provide a framework for the appropriate timing of the first assessment of a patient's response to treatment [Table 3]. Clinical practice guidelines encompassing a broad range of interventions for a variety of spinal, upper and lower extremity conditions most commonly recommend assessment for clinical improvement within 4-6 weeks following the initiation of an episode of care.[16-33] The median time of the first assessment of treatment response was 4 weeks in systematic reviews of headache,[34] neck pain,[34,35] low back pain,[34,36-38] osteoarthritis,[34,39] rehabilitation following hip and knee arthroplasty,[41] shoulder disorders,[34,42] and post-stroke rehabilitation.[42] Services included various exercise regimes, manual therapy, acupuncture, traction and supports.

Table 3. Timing of first outcome assessment following baseline evaluation

Source/author (date)	Condition or region	Timing of 1st assessment (mean/median [range])	Interventions
Clinical Guidelines			
AAOS (2013)[16]	Knee OA	8 weeks [4-8 weeks]	Exercise*, manual therapy^, physical agents‡, acupuncture, massage
ACP/APS (2007)[17]	LBP	4 weeks	Broad range of skilled therapy services
ASSET (2010)[18]	Shoulder (surgery)	6 weeks (end of phase 1 of rehabilitation schedule)	Post-operative rehabilitation therapy services
VA/DoD (2014)[19]	Hip & knee OA	4 weeks	Manual therapy, acupuncture
CCGPP (2016)[20]	LBP (acute/subacute/chronic)	2-4 weeks	Scope of services provided by chiropractors
ICSI (2012)[21]	LBP (acute/subacute)	1-2 weeks	Manual therapy
Washington State (2013)[22]	Shoulder conditions	4-6 weeks	Exercise and manual therapy
Barton (2015)[23]	Patellofemoral pain	6 weeks [4-8 weeks]	Taping, exercise, foot orthoses
Colorado State (2012)[24]	Complex Regional Pain Syndrome (CRPS Types I and II)ψ	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2012)[25]	Chronic pain	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2013)[26]	Traumatic brain injury	3-4 weeks	Broad range of skilled therapy services
Colorado State (2014)[27]	LBP	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2014)[28]	Cervical spine conditions	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2015)[29]	Thoracic outlet syndrome	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2015)[30]	Shoulder conditions	3-4 weeks	Broad range of non-interventional and interventional services

Colorado State (2016)[31]	Lower extremity conditions[†]	3-4 weeks	Broad range of non-interventional and interventional services
Colorado State (2017)[32]	Cumulative trauma conditions[§]	3-4 weeks	Broad range of non-interventional and interventional services
KNGF [Royal Dutch Society for Physical Therapy] (2017)[33]	Neck pain	3 weeks (pain) 6 weeks (disability)	Broad range of skilled physical therapy services
Systematic Reviews			
Gross (2015)[35]	Mechanical neck disorders (with/without headache or radicular symptoms)	6 weeks (short-term follow-up = 1 day to 12 weeks)	Exercise[*], manual therapy[^], acupuncture, traction, cervical support collar/pillow, guided movement, Qigong
Paige (2017)[37]	LBP (acute)	2 weeks [3-35 days]	SMT compared to a broad range of interventions and controls
Saragiotto (2016)[38]	LBP (chronic)	4-10 weeks	Motor control exercises compared to other types of exercise
Liddle (2015)[36]	LBP and pelvic pain during pregnancy	4 weeks [1 day-16 weeks]	Exercise[*], manual therapy[^], acupuncture, taping, pelvic belt, yoga, progressive relaxation, TENS
Chen (2016)[42]	Stroke (balance)	5 weeks [2-8 weeks]	Sling exercise training
Xu (2017)[39]	Knee OA	4 weeks [2-8 weeks]	Manual therapy
Steuri (2017)[41]	Shoulder impingement	4 weeks [1 day-18 weeks]	Broad range of non-interventional and interventional services
Skoffer (2015)[40]	THA and TKA	7 weeks [4-9 weeks]	Post-surgical rehabilitative progressive resistance exercise
Vickers (2017)[34]	Chronic headache; Back & neck pain; Osteoarthritis; Shoulder pain	4 weeks	Acupuncture

Legend

[*] Exercise = strength, aerobic, endurance, stabilization, agility, kinesthesia, proprioceptive training, progressive resistance, general fitness, postural, land/water, weight bearing/non-weight bearing.

[^] Manual therapy = manipulation, mobilization, myofascial techniques

[ł] Physical agents = ultrasound and electrotherapeutic modalities

[Ψ] Complex Regional Pain Syndrome = CRPS Type I (reflex sympathetic dystrophy [RSD]); CRPS Type II (causalgia)

[†] Lower extremity conditions = foot & ankle; knee; hip & leg

[§] Cumulative trauma conditions = aggravated OA of the digits, hand or wrist; De Quervain's disease; epicondylitis; extensor tendon disorders of the digit or wrist; flexor tendon disorders of the digit or wrist; triangular fibrocartilage complex tear; trigger digit; carpal tunnel syndrome; cubital tunnel syndrome; Guyon canal (tunnel) syndrome; posterior interosseous nerve entrapment; pronator syndrome; radial tunnel syndrome

In addition to information gleaned from guidelines and systematic reviews, research using latent class analysis (LCA) – a statistical technique that can be applied to the reporting of PROMs – has been able to determine different trajectories over the time course of an episode of care.[43] LCA typically involves more frequent (eg, weekly) reporting of treatment response, providing more definitive insight about the timing of outcome assessments for detecting clinically meaningful improvement.

While most research on measuring recovery patterns in musculoskeletal disorders has been centered on people with pain in specific anatomical pain sites, common recovery patterns or trajectories of pain and function over time have been identified. De Vos Andersen, et al (2017) evaluated a broad range of musculoskeletal conditions affecting the trunk, and upper/lower extremities.[44] The primary pain site diagnosis had little influence on the ability to assess a satisfactory outcome. The trajectory of improvement on the outcomes of pain intensity, disability and sick leave (temporary health-related income support) was similar to those previously observed in low back pain and exceeded a common threshold of clinically relevant important change (i.e. > 30% improvement from baseline).

Trajectories of neck and low back pain have been most commonly investigated.[45-48] Ninety percent of patients with neck pain or low back pain presenting to chiropractors were shown to have a 30% improvement within 6 weeks.[45] Seventy four percent of individuals with neck pain experienced a 30% reduction in pain within 3 weeks of starting care. These individuals were classified as 'recovering from mild baseline pain'. Almost sixty percent of those with low back pain, all classified as 'recovering from mild baseline pain', demonstrated a 30% reduction in pain within 3 weeks. A review of trajectory studies for low back pain showed that early clinically meaningful improvement was the common across all subgroups regardless of long-term recovery patterns.[49] The 'typical' trajectory demonstrated definite improvement within in the first 5–6 weeks of a care episode.

Assessing Clinical Change:

A critical consideration in the determination of MTB is the assessment of clinical importance or meaningfulness of change in scores that occurs during an episode of care. It is broadly recognized that patients' perspectives are essential in making clinical decisions and judging the results of treatment.[9] There are no objective biological markers for assessing patient-important outcomes such as pain intensity or functional limitations. Consequently, the most accurate and reliable method for detecting clinically meaningful change is based on the interpretation of PROMs.[50]

However, it is difficult to interpret changes in PROM scores since they lack an absolute reference standard, and there is wide inter-person variability in self-reports of symptoms and function.[50] Therefore, it is important to interpret PROMs using their minimal clinically important difference (MCID), which can be used as a criterion for assessing the beneficial effects of a therapy.

The minimum clinically important difference (MCID) was first defined in 1989 as ''the smallest difference in score in the domain of interest which patients perceive as beneficial''.[51] While others have described similar terms (eg, minimal clinically important change) and definitions, the fundamental idea has remained the same: MCID is a calculated threshold value in an outcome of interest that patients and clinicians perceive as clinically meaningful; i.e., a value that demonstrates an appreciable change in outcome.[52]

The basis for quantification and standardization of MCID is to minimize the variability in clinician judgment of patient 'change' following treatment.[53] The inaccurate assessment of 'change' has been shown to mitigate the quality of clinician decision-making.[54]

MCID for the most common standardized outcome assessment tools have been calculated [Table 4].[55-64] An international panel of experts stated that 30% change from baseline may be considered a clinically meaningful improvement when comparing before and after patient-reported outcomes scores.[65] The minimal [clinically] important change values adopted by the VII International Forum on Primary Care Research on Low Back Pain (Amsterdam, June 2006) are: 15/100 for the Visual analogue Scale, 2/10 for the Numerical Rating Scale, 5/24 for the Roland-Morris Disability Questionnaire, 10/100 for the Oswestry Disability Index, and 20/100 for the Quebec Back Pain Disability Questionnaire.[65]

Table 4: MCID for commonly employed outcome measures

Citation	Domain	Outcome Tool	Study Characteristics	MCID	F/U Period
Farrar [55]	Pain	NRS	- N = 2724 - Retrospective analysis of controlled trials for: diabetic neuropathy, postherpetic neuralgia, chronic LBP, fibromyalgia, osteoarthritis - PGIC used as an external criterion	· 30% change from baseline · If baseline score was at least 4/10 then a 2 point change · Baseline was less than 4/10 then 0.5	5-12 weeks
Turner [56]	Pain	VAS	- N = 1124 - Work-related LBP - Telephonic survey	· Baseline was at least 5/10 then a 2 point change (based on change in perceived disability) · Baseline was less than 5/10 then a 1 point change was clinically relevant based upon perceived change in function	N/A
Hagg [57]	Pain	VAS	- N = 289 - RCT - Chronic LBP with or without LE complaints - Patients treated surgically and non-surgically	· 18-19 point change in 100mm scale	2 years
Fritz [58]	Function / Disability	ODI	- N = 67 - Work-related Acute LBP with and without LE pain - PGIC used as an external criterion - Physical Impairment Scale: supported the construct validity of the PGIC	· 6%	4 weeks
Hagg [57]	Function / Disability	ODI	- N = 289 - RCT - Chronic LBP with or without LE complaints - Patients treated surgically and non-surgically	· 10%	2 years
Meade [59]	Function / Disability	ODI	· N = 50 · RCT	· 8%	Weekly (6 weeks)
Taylor [60]	Function / Disability	ODI	· N = 318 · LBP with and without sciatica · Surgical and non-surgical cases · 75% chronic	· 16.3%	Pats receiving PT and/or injections = 2 months Surgical pats = 6 months All @ 12 and 24 months
Stratford [61]	Function / Disability	NDI	· N = 49 · Convenience sample from multiple physical therapy outpatient clinics · Eligibility criteria not described	· 10%	1 to 3 weeks
MacDermid [62]	Function / Disability	NDI	· Systematic Review · N = 37 primary studies, 3 reviews, and 1 in-press paper were analyzed · Rankings of quality and descriptive syntheses were performed	· 10% for uncomplicated neck pain · 20% for cervical radiculopathy	Varied
Binkley [63]	Function / Disability	LEFS	· N = 107 · Convenience sample from twelve physical therapy outpatient clinics · All LE conditions included · PGIC used as an external criterion · Correlated with SF-36 physical function score	· 9 scale points	At 1-2 days following baseline Weekly (4 weeks)
Beaton [64]	Function / Disability	DASH	· N = 200 · Diverse subject group having either wrist/hand or shoulder problems	· 15 scale points	3 months

Legend:

- NRS = Numerical Rating Scale
- VAS = Visual Analog Scale
- ODI = Oswestry Disability Index (Revised)
- NDI = Neck Disability Index
- LEFS = Lowe Extremity Functional Scale
- DASH = Disabilities of the Arm, Shoulder and Hand Questionnaire

Factors that have been shown to influence MCID include the duration and severity of complaints at the initial visit (index visit), and the timing of data collection. In general, acute (recent onset) presentations require a larger difference between baseline and subsequent assessments to be viewed as meaningful. For example, "If a numerical rating scale (NRS) is used it seems reasonable to suggest that the MCIC [MCID] should at least be 3.5 and 2.5 for patients with acute and chronic low back pain, respectively."[9] Similarly, patients who present with low levels of pain or disability at the index visit would need lesser changes at follow-up for MCID to be achieved.[61,66,67] Additionally, the time interval between outcome assessments may influence the magnitude of change. In general, longer time periods in comparison to lesser intervals (6 weeks vs. 2 weeks) between measurements would be expected to demonstrate greater change scores.[68]

Global perceived effect (GPE) scales can be utilized as a method of determining directly how much the patient perceives his or her condition to be improved. These scales require the patient or subject to state by how much their condition has improved at time points throughout and at the end of the intervention. As such, this method is considered to be a retrospective outcome measure.[69] In contrast, standardized assessments of pain and function can be seen as prospective outcome measures, as they are administered pre- and post-treatment.[70]

Various GPE scales have been described in the literature. The 7-point scale GPE scale has emerged as a commonly used measure for the direct reporting of condition improvement.[71] Physical outcomes and PROMs have shown a relationship with GPE scales.[58] On a 7-point GPE scale, category six or 'much better or improved' represents the threshold for clinically important improvement.[55,67,71-75] "Therefore, patients that rate themselves as 'slightly improved or better' are not considered to be significantly improved."[71]

It has been recommended that the selection of measures should be composed of a retrospective method (GPE scale) and prospective methods (pain and functional questionnaires), in order to classify patients as either clinically improved or clinically not-improved.[71] This approach to interpreting PROMs can be applied to the determination of MTB. [*See: Decision Guide for Informing Judgments in Making UR Determinations: Integration of the Global Rating Scale with Core Outcome Measurements*]

Assessing the Probability of Further Meaningful Improvement

The probability of further meaningful improvement ties into the three preceding elements for assessing maximum therapeutic benefit (MTB). Further meaningful improvement can occur only when there is a potential for MCID. Standardized outcome measures provide the template for identification of MCID. The timing of assessment should be consistent with realistic expectations i.e., short-term goals.

Judgments about the probability of further meaningful clinical improvement with ongoing treatment can be informed by research describing factors associated with the patterns of improvement and the longitudinal trajectories of a condition.

Patterns of pain and functional improvement have been systematically assessed for individuals diagnosed with nonspecific low back pain.[76] The review included a wide variety of treatments ranging from simple advice to intensive multidisciplinary rehabilitation pain management programmes including examples such as medications, acupuncture, chiropractic, and transcutaneous electrical nerve stimulation (TENS). There was a similar pattern of initial rapid improvement at 6 weeks; after which, only small further improvements

for both pain and functional disability were seen regardless of the intervention. A subsequent systematic review and meta-analysis of randomized clinical trials and observational studies examined the course of non-specific low back pain.[77] The results were no different: a rapid improvement in the first 6 weeks followed by a smaller further improvement.

A simple clinical prediction model – assessed after the first week of an episode of care for low back pain – has been shown to reliably inform determinations about the probability of further clinically meaningful improvement for individual patients.[78] This model uses five variables: duration of current episode, number of previous episodes, depression score, baseline pain intensity, and magnitude of change in pain level at 1-week. This information has been shown to be able to predict, after 1 week of care, the likelihood of further clinical improvement (recovery) from an episode of acute LBP at 1 month and 3 months. This prediction model is consistent with a previous study that reported pain intensity, duration of pain and number of previous episodes as important factors in predicting further treatment response.[79] Further, the application of this model performed better than clinicians' judgment in predicting treatment response.

For acute and chronic non-spinal musculoskeletal pain conditions, generic factors appear to play an important role in assessing the probability of further MCID, regardless of the location of pain.[80] Generic factors predicted outcome over different time periods (3 months and 12 months) and for both acute and chronic non-spinal musculoskeletal pain. The most consistent predictors of poor outcome were having had the same complaint in the previous year, a lower level of education, lower scores on the Short Form 36 vitality subscale, using pain medication at baseline, and being bothered by the complaint more often in the past 3 months.

Other studies have investigated the predictive ability of more discrete variables. A $\geq$2 point change (on an 11-point numeric rating scale) from baseline to after the second physical therapy visit was associated with further positive outcomes (pain and function) in patients who receive a manual therapy approach.[81] Similarly, patients with low back pain undergoing chiropractic treatment, who are likely to respond to further care, demonstrate early improvement.[82] Patients with chronic and acute pain reporting that they were "much better" or "better" on the Patient Global Impression of Change scale at 1 week after the first chiropractic visit were 4 to 5 times more likely to be improved at both 1 and 3 months compared with patients who were not improved at 1 week. Patients with acute pain reported more severe pain and disability initially but recovered faster. Patients with chronic and acute back pain both reported good outcomes, and most patients with radiculopathy also improved.

Another component in the determination of MTB, as it relates to the potential for further meaningful improvement, is the consideration of end-points for skilled professional services. Skilled care may be necessary: 1) to improve a patient's current condition; 2) to prevent or slow further deterioration of the patient's condition; or 3) to help a person keep, learn or improve skills and functioning for daily living to maintain the patient's current condition. A determination that MTB has been reached from the skilled services of a qualified health care provider is appropriate, when none of these conditions are met and/or recovery milestones are reached and progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through a general exercise program or other self-care.[66,83,84]

Two "Decision Guides" have been developed to inform utilization review (UR) determinations. The *MTB – Decision Making Flow* sequentially describes the serial judgments required to make consistent determinations about MTB. The *Integration of the Global Rating Scale with Core Outcome Measurements* provides guidance in the interpretation of standard outcome measures (pain and physical function) in the context of a global measurement of satisfaction with treatment outcome. Four possible scenarios are described. The complexity of UR decision making, clinical considerations, and the degree of confidence in rendering a determination based on the information at hand are incorporated into this guide. Both Decision Guides are appended to this document.

Consultative Care

Consultative care (chronic condition management or supportive care) may be appropriate for individuals who were discharged from continuing skilled care services after reaching MTB and are subsequently unable to sustain self-sufficient and independent management of his/her chronic condition.[85,86] The medical necessity of consultative care must be documented in the patient's health care record.

Criteria that support the medical necessity of consultative care include all of the following:

- Treatment success (≥50% improvement in pain and/or function) was previously achieved during the initial episode of care [87,88]
- Clinically relevant pain and/or functional deficits persisted after achieving MTB [Whalen]
- Alternative treatment options including referral were considered
- The patient was educated in appropriate post-discharge self-management approaches
- A "flare" or "recurrence" (see Definitions) has occurred
- Skilled care services are aimed at supporting a return to prior MTB outcomes
- Treatment is not considered to be "maintenance care"

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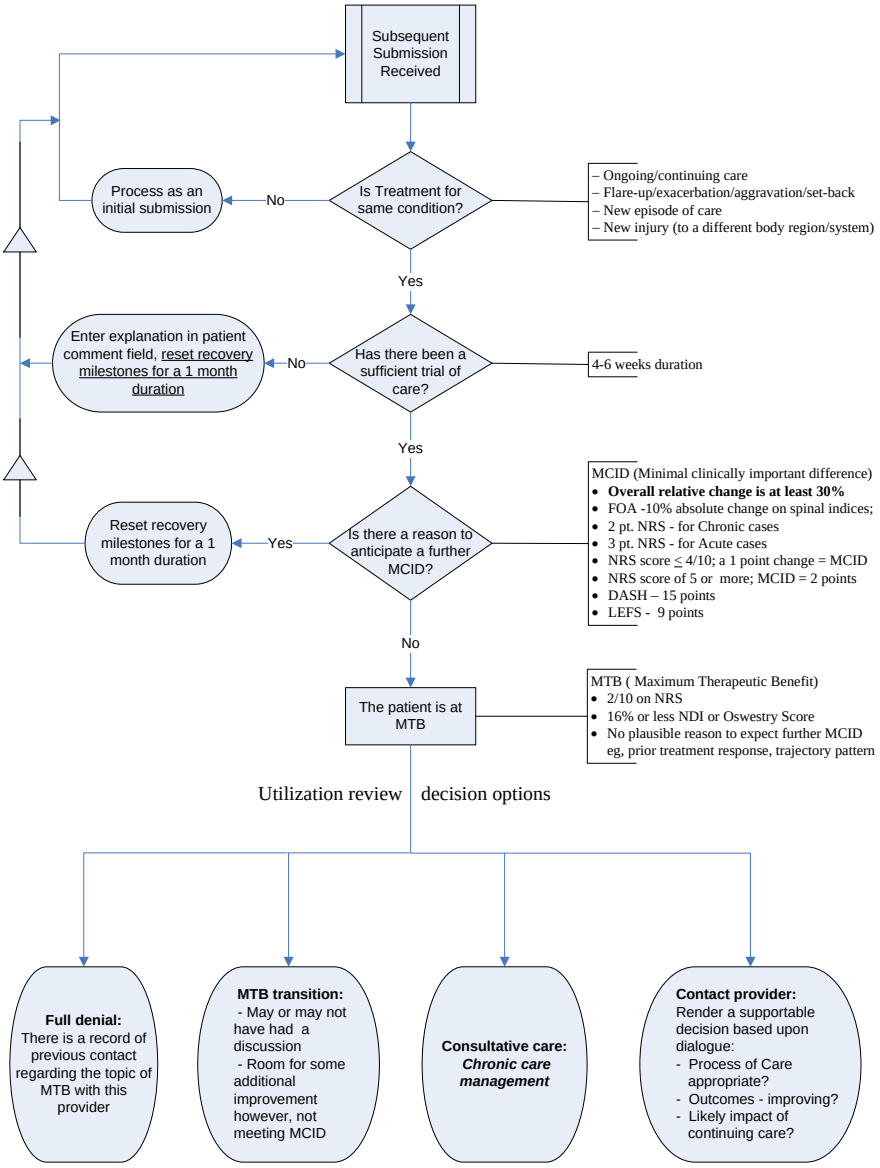
Appendix

MTB – Decision Making Flow



Decision Guide for Informing Judgments in Making UR Determinations: *Integration of the Global Rating Scale with Core Outcome Measurements*

Scenario A

Core Outcome Measures and Global Rating Scale AGREE		
All outcomes favor the same direction i.e., improved or not improved		
UR Decision Making	**Clinical Considerations**	**Confidence**
Straightforward: *Improved or Not improved*	Patient perception is aligned with valid and reliable outcome assessment tools (OA). Care management should be in accord with the likelihood of MCID with ongoing care	High

Scenario B

Core Outcome Measures AGREE and Global Rating Scale DISAGREE		
Core outcome measures are consistent for clinically meaningful improvement and GRS score is ≤ 5		
UR Decision Making	**Clinical Considerations**	**Confidence**
Straightforward: *Improved*	Patient satisfaction with outcome is at variance with standard OA. Final status may be influenced by encouraging provider/patient discussion	High

Scenario C

Core Outcome Measures AGREE and Global Rating Scale DISAGREE		
Core outcome measures are consistent for NO clinically meaningful improvement and GRS score is ≥ 6		
UR Decision Making	**Clinical Considerations**	**Confidence**
Complex: *Improved → Not improved*	Lack of improvement as reported in standardized OA conflicts with the patient self-report, which typically is associated with a moderate-large treatment effect. Peer-to-peer outreach is indicated to ascertain the most likely 'change-status' of the patient. In the absence of peer-to-peer contact, consider a transitional determination.	Low to Moderate

Scenario D

Core Outcome Measures DISAGREE		
Outcome measures for pain and disability are at variance. The GRS is in agreement with one of the standard outcome assessments		
UR Decision Making	**Clinical Considerations**	**Confidence**
High Complexity: *Improved → Not improved*	The GRS can be helpful with informing judgment. Other factors to consider include: • the relative values placed upon types of outcomes i.e., pain reduction for acute vs. change in function for chronic • magnitude of clinical change in standard OA e.g., large change in pain level vs. modest change in pain • magnitude of change in GRS • probability of further MCID	Moderate

Policy History/Revision Information

Date	Action/Description
7/2006	Original effective date
12/04/2006	Annual review completed
4/10/2008	Annual review completed
11/11/2008	Policy header rebranded, "OptumHealth Care Solutions – Physical Health
1/15/2009	Policy placed into new format
4/30/2009	Annual review completed; MTB -Decision Guide added
7/16/2009	Policy revised and approved by QIC; Nonspinal disorders added to cited literature; Definitions updated; References updated; Decision Guide for interpreting standardized outcomes assessment tools in the context of global ratings was added; Plain Language Summary updated
4/08/2010	Annual review completed
10/26/2010	Policy rebranded to "OptumHealth Care Solutions, Inc. (OptumHealth)"
4/07/2011	Annual review completed
4/19/2012	Annual review completed
4/18/2013	Annual review completed
4/17/2014	Annual review completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc."
4/16/2015	Annual review completed
4/21/2016	Annual review completed
4/20/2017	Annual review completed; Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review completed; Background, Definitions, Summary sections, and MTB decision flow revised to reflect advances in the body of evidence.
4/25/2019	Annual review completed; no significant changes made to the document
4/23/2020	Annual review completed; Updated Definition of Flare-up; Added consultative care criteria to the Background section.

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.

PLAIN LANGUAGE SUMMARY

Maximum Therapeutic Benefit

Utilization Management Policy # 84

Plain Language Summaries are a service provided by *Optum* by OptumHealth Care Solutions, LLC* to help patients better understand the complicated and often mystifying language of modern healthcare.

Plain Language Summaries are presented to supplement the associated clinical policy or guideline. These summaries are not a substitute for advice from your own healthcare provider.

What is maximum therapeutic benefit and what is known about it so far?

Musculoskeletal pain, especially spinal pain is a common problem. Traditional nonsurgical treatments that are helpful for some patients with musculoskeletal pain include physical therapy, manipulation (chiropractic), exercise and drugs (pain killers, anti-inflammatory drugs, and muscle relaxants). It is important to determine if a particular treatment is helping a person improve *(decreased pain and increase abilities to perform daily activities)*. Most treatments reach a point where no further improvement can be expected. **This is called the point of maximum therapeutic benefit (MTB)**. MTB can be reached when complaints either fully resolve, or when pain and/or disability persist – even with ongoing treatment.

It is not difficult or burdensome to measure improvement resulting from treatment. There are enough resources available for a healthcare provider to know when and how to measure improvement. With this information, the reasonable likelihood of additional improvement can be determined.

Most healthcare benefit certificates do not include treatment that is not resulting in a reasonable expectation of further improvement from that particular treatment.

How was Maximum Therapeutic Benefit evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for policies and articles that provided information about 1) when during the course of care is it reasonable to measure for improvement; 2) methods to measure improvement in pain and/or disability; 3) the probability of further improvement with a continuation of treatment; and 4) the likelihood that stopping treatment will result in a worsening of either pain or disability.

After gathering and analyzing this information, a policy was presented to a series of committees that included independent health care practitioners.

What did the work group find?

- Most individuals can expect to notice measurable improvement in pain and/or disability early during the course of care – within 2 to 6 weeks after beginning treatment.
- If improvement has not occurred with 6 weeks of treatment, it is highly unlikely that continuing treatment will be helpful.
- When initial improvement did occur, many studies showed no additional lasting improvement beyond 6 to 12 weeks of treatment.
- Most flare-ups resolve quickly – within a few days to 3 weeks.

What were the limitations of the information?

While there is increasing amount of information about nonspinal conditions e.g., shoulder, knee, ankle, etc., the majority of research is related to spinal conditions (low back and neck pain, sciatica, etc.). The timelines for improvement may not be applicable to some types of post-surgical care.

What are the conclusions?

An individual has reached MTB when after at least 4 to 6 weeks of treatment one of the following is present:

- Complaints have resolved or stabilized
- There has been improvement; however, there is no reason to expect further improvement with the same care
- There has not been improvement in pain and/or disability (based on standardized assessments)
- There is insufficient information in the healthcare record to determine that improvement has occurred.

What are the options once MTB has been reached?

Once MTB has been reached it is the responsibility of the healthcare provider to:

a) Revise the plan of care based upon current research evidence

b) Discharge a patient from active/therapeutic care

c) Recommend an alternate type of treatment by a different healthcare provider